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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,897	04/06/2006	Augusto Amici	2503-1207	3387

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YOUNG & THOMPSON
209 Madison Street
Suite 500
ALEXANDRIA, VA 22314

EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
09/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,897	AMICI ET AL.	
	Examiner	Art Unit	
	Michael Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-26* is/are pending in the application.

4a) Of the above claim(s) *23-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 5/13/2009 is acknowledged. The traversal is on the ground(s) that the claimed vectors in Groups I-XIV share a common technical feature, a chimeric human/rat p185neu fusion protein, that is a contribution over the prior art, and thus should not be restricted. Furthermore, Groups XV and XVI share a technical feature with Group II and X-XIV that is a contribution over the prior art, as set forth above, and thus should not be restricted. Groups I and III-IX do not constitute an undue search burden. This is not found persuasive because the technical feature linking the Groups as set forth in the restriction requirement stands. The claims are worded in a broad manner, and do not require only the exact sequences set forth in the various SEQ ID NOs, but rather, appear to include fragments of such, and additional sequences may be present. Thus they are considered to not share a special technical feature for reason of record and reason set forth below. This is all that is required for restriction under 371 rules, search burden is not a consideration.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 22 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 22 are dependent upon canceled claims 7 and 8. It is thus unclear what limitations are included in the claims. They have examined as dependent upon claim 20 in the interest of compact prosecution.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-17 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al, (Cancer Res., 1998, cited by applicants).

The claims recite a DNA vector containing a sequence encoding a fragment. wherein the sequence is selected from one of fourteen SEQ ID NOs. As far as can be determined, the elected invention, SEQ ID NO: 2, comprises rat sequences encoding p185neu from residues 17-1276. It appears that SEQ ID NO: 2 is a chimera prepared from rat and human sequences encoding p185neu, but a description of SEQ ID NO: 2 in the specification regarding which portions are human and which are rat is lacking. The instant claims are worded with open language, i.e. the vectors "contain" fragments of SEQ ID NO: 2, hence, a DNA vector comprising the entire $p185^{neu}$ rat gene is considered to be anticipatory of the claimed fragments. The term "containing" is interpreted as comprising in this instance. Chen et al teach various DNA vectors encoding the rat p185neu sequence, or fragments thereof under control of the CMV promoter (see the abstract, Introduction, and page 1966, first column, first full ¶). The plasmids were

prepared in saline for injection into mice (page 1967, first column, first full ¶), which is considered a pharmaceutically acceptable excipient, and in a form for injection (claim 22) or parenteral injection (claim 21).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (Cancer Res., 1998, cited by applicants) in view of Krieg et al (U.S. patent 6,653,292).

The teachings of Chen et al are as above and applied as before. Chen et al do not teach the inclusion of CpG motifs in the DNA vectors. Furthermore, Chen et al is directed towards the DNA vaccination of mice in order to treat tumors (title, abstract, and introduction)

Krieg et al teach the use of CpG motifs in DNA expression vectors in order to increase the immune response to the injected DNA. See the abstract, col. 41 - col. 42, line 17 in particular.

The claimed vectors are essentially disclosed by Chen et al with the exception of the inclusion of CpG motifs. The ordinary skilled artisan, seeking to improve the vaccination efficacy of the DNA vectors of Chen et al, would have been motivated to use CpG motifs because Krieg et al teaches these to be a well known of doing so. It would have been obvious for the skilled artisan to do this because of the known benefit of generating an efficacious immune response to p185neu, as taught by Chen et al. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633